12 Safety and Efficacy - Premarket Notification 510(k) Summary

510(k) Summary as required per 807.92.

12.1 Submitter Details

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Date of submission: 12th February 2001

12.2 Device Name and Classification

12.2.1 Device name

Nx-301 system

12.2.2 Device Common Name

Programmable Diagnostic Computer

12.2.3 Classification, product code

Class: II
Product Code: DQK CFR: 870.1425 Programmable Diagnostic Computer

12.3 Predicate Device Information

The device has been compared to the following cleared devices:

Company	Device	510(k)
Nexan Ltd	Nx-300	K003520
ELA Medical Inc	Syneflash™ (recorder) Syneview™ (analysis software)	K990727
Reynolds Medical	Pathfinder 700	K951902

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12.4 Device Description

The Nx-301 system is a non-invasive ambulatory patient monitoring system for recording multiple physiological parameters from patients who may be located at home or in an alternate care setting. The Nx-301 system continuously gathers physiological data from a sensor band (Nexi) and, additionaly a Blood Oxygen sensor attached to either the patient's ear or finger and transmits the data wirelessly (Nexi-Clip) to a Signal Transfer Unit (PDA) where the data are recorded and stored. The data is transferred to a Base Station Unit (BSU) by docking the PDA in the BSU. Additionally, the BSU has interfaces for auxiliary sensors – spirometer, blood pressure monitor and Weight , which are used for recording point in time lung function, blood pressure and weight measurements accordingly. A Call Discriminator Unit within the BSU enables incoming telephone calls to be correctly routed to either the BSU or a telephone handset. The BSU also contains the analyser software for ECG and Respiration.

The data are transmitted for display, monitoring and storage on a computer Telemonitoring Station (TMS) running the Nexoft application software at a distant location known as the Telemonitoring Centre. This data transfer is under the control of the Health Care Professional (HCP) at the TMS. Raw data may be transferred in real time to enable the HCP to check on the quality of the physiological data being recorded and/or the status of the patient. Normally data is transferred at a scheduled time after the end of a patient data recording session. Once transferred to the TMS the data can subsequently be displayed for analysis by the HCP. The Nx-301 system enables the HCP to print reports of raw data

12.5 Intended Use

The Nx-301 is a medical device that measures and/or records continuously a patient's respiration (impedance), oxygen saturation (SpO_2), and electrocardiogram (ECG); stores the data for periods up to 24 hours (including periods of ambulation); and has the capability to periodically transmit the data via telecommunication from the patient's home to a physician or other healthcare professional. The Nx-301 can also provide point in time measurements of blood pressure, body weight, and spirometry (PEF, FVC, and FEV1). Additionally, the Nx-301 system features buttons that can be used by the patient to place "event markers" on the time scale of the recorded data to record the moment of occurrence of specific events, as may be directed by the physician or healthcare professional.

Thus, the Nx-301 provides measurements of these parameters in an ambulatory setting and transmission of the data to a physician or other healthcare professional in another setting (e.g. a healthcare facility or central information monitoring facility). In this manner, the Nx-301 facilitates long-term monitoring of patients' cardiac rhythm and respiration, including respiration rate, changes in impedance amplitude and the level of SpO2.

The device contains no alarm functions should not be used as an apnea or cardiac monitor and. Any excessive artefact that is generated should be omitted. The Nx-301 does not replace the care of a physician or other healthcare professional.

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12.6 Non-clinical performance data for equivalence

12.6.1 ANSI/AAMI EC38

Compliance testing of the Nx-301 system to ANSI/AAMI EC38 Ambulatory Electrocardiographs has been conducted.
The report (300-TR-011) concludes that the Nx-301 system is a Type I ambulatory electrocardiograph and is compliant with ANSI/AAMI EC38.

12.6.2 ANSI/AAMI EC57

Compliance testing of the Nx-301 system to ANSI/AAMI EC57 Ambulatory Electrocardiographs has been conducted.
The report (300-TR-014) concludes that the Nx-301 system is compliant with ANSI/AAMI EC57.

12.7 Clinical performance data for equivalence

Not applicable

12.8 Predicate Device Comparison

The comparison of intended use and technological features of the Nx-301 system with cleared devices taken together with the validation results, performance tests and other information in this submission indicate the Nx-301 system is substantially equivalent in safety, effectiveness and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 4 2001

Nexan Ltd.
c/o Dr. David L. West
Quintiles Consulting Inc.
1801 Rockville Pike, Suite 300
Rockville, MD 20852

Re: K010424
Trade Name: Nexan System, Model Nx-301
Regulatory Number: 21 CFR 870.2300
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: June 5, 2001
Received: June 6, 2001

Dear Dr. West:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to

comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

13 Indications for Use Statement.

510(k) Number (if known): K010424

Device Name: Nx-301 PROGRAMMABLE DIAGNOSTIC COMPUTER

Indications For Use:

The Nx-301 is a medical device that measures and records continuously a patient's respiration (impedance), oxygen saturation (SpO_2), and electrocardiogram (ECG); analyses and stores the data for periods up to 24 hours (including periods of ambulation); and has the capability to periodically transmit the data via telecommunication from the patient's home to a physician or other healthcare professional. The Nx-301 can also provide point in time measurements of blood pressure, body weight, and spirometry (PEF, FVC, and FEV1). Additionally, the Nx-301 system features buttons that can be used by the patient to place "event markers" on the time scale of the recorded data to record the moment of occurrence of specific events, as may be directed by the physician or healthcare professional. The Nx-301 generates reports on the results of the data analysis and provides an editing facility to allow manual overread by a trained healthcare professional.
Thus, the Nx-301 provides measurements of these parameters in an ambulatory setting and transmission of the data to a physician or other healthcare professional in another setting (e.g. a healthcare facility or central information monitoring facility). In this manner, the Nx-301 facilitates long-term monitoring of patients' cardiac rhythm and respiration, including respiration rate, changes in impedance amplitude and the level of SpO2.
The device contains no alarm functions and should not be used as an apnea or cardiac monitor. Any excessive artefact that is generated should be omitted. The Nx-301 does not replace the care of a physician or other healthcare professional.

Federal Law (US) Restricts this device to sale by or on the order of a physician

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010424